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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,845	10/15/2003	Michael T. Lotze	UPT-004	9535

22832 7590 12/14/2005

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EXAMINER

JUEDES, AMY E

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/688,845

Applicant(s)

LOTZE ET AL.

Examiner

Amy E. Juedes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's response to the restriction requirement issued on 9/7/05 is acknowledged. However, the restriction requirement issued on 9/7/05 is hereby vacated. The following is a new requirement for restriction.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-6, 9-18, and 21-26, drawn to a method of inhibiting a tumor or metastasis of a tumor with an antigen presenting cell and an immunostimulatory cytokine; classified in Class 424, subclass 85.1.

II. Claims 1-26, drawn to a method of inhibiting a tumor or metastasis of a tumor with an antigen presenting cell and an nucleic acid encoding an immunostimulatory cytokine; classified in Class 514, subclass 44.

III. Claims 1-6 and 10-12, drawn to a method of treating an infection lesion with an antigen presenting cell and an immunostimulatory cytokine; classified in Class 424, subclass 85.2.

IV. Claims 1-8 and 10-12, drawn to a method of treating an infection lesion with an antigen presenting cell and an nucleic acid encoding an immunostimulatory cytokine; classified in Class 424, subclass 93.7.

V. Claim 27, drawn to a composition comprising an antigen presenting cell and an immunostimulatory cytokine; classified in Class 435, subclass 325.

VI. Claim 27, drawn to a composition comprising an antigen presenting cell and a nucleic acid encoding an immunostimulatory cytokine; classified in Class 536, subclass 23.1.

4. Groups V-VI are different products. A composition comprising a nucleic acid and a composition comprising a protein cytokine differ with respect to their structures and physicochemical properties.

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5. Groups I-IV are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods comprising different method steps, different reagents, resulting in different endpoints. For example, the methods of group I and III require distinct reagents (i.e. a protein cytokine) from the methods of groups II and IV (i.e. a nucleic acid encoding a cytokine). Furthermore, the methods of groups I-II require a patient with a tumor, while the methods of groups III-IV require a patient with an infectious lesion.

6. Groups V and I, III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition comprising an antigen presenting cell and immunostimulatory cytokine can be used to generate T cell lines in vitro.

7. Groups VI and II, IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition comprising an antigen presenting cell a nucleic acid encoding an immunostimulatory cytokine can be used to generate T cell lines in vitro.

8. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by their recognized divergent subject matter. Further, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct reagents. Therefore restriction for examination purposes as indicated is proper.

Species Election

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9. This application contains inventions drawn to patentably distinct species. Applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

10. Applicant is required to elect:

A) a specific species of antigen presenting cell, such as one of those listed in claims 2-5.

B) a specific immunostimulatory cytokine, such as one of those listed in claim 6.

And list all claims readable thereon, including any claims subsequently added. Currently claims 1, 7-13, and 18-27 are generic with respect to an antigen presenting cell, and claims 1-5, 8-17, and 19-27 are generic with respect to an immunostimulatory cytokine.

These are distinct species because their phenotypes and functions are different. For example, a B cell expresses immunoglobulin, while a dendritic cell does not. Transforming growth factor- β is an immunosuppressive cytokine, while interferon- γ is an immunostimulatory cytokine.

11. A telephone call was made to Michael Brodowski on 11/17/05 to request an oral election to the above restriction requirement, but did not result in an election being made.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or

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identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

15. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re*

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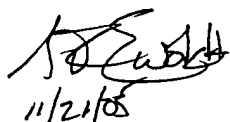
Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Amy E. Juedes whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.
Patent Examiner
Technology Center 1600
November 18, 2005


11/21/05
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER